

Questions and Answers on Bottled Water and Vended Water in California

This list of “frequently asked questions & answers” is intended to be a convenient place to find answers to common questions about the regulation of bottled water and vended water in California. The answers below represent the current thinking of the Department of Health Services’ Food and Drug Branch (FDB). They do not confer any rights, privileges, benefits or immunities for or on any person nor do they bind FDB or the public.

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1. What is bottled water?

Answer (A):

Bottled water is water sold or distributed to consumers in sealed containers for drinking, culinary, or other purposes involving a likelihood of being ingested by humans. Bottled water must be bottled only at a licensed water bottling plant.

2. What is vended water?

A: Vended water is water dispensed by a water vending machine, retail water facility (or store), water from a private water source, or water delivered by a water hauler for drinking, culinary, or other purposes involving a likelihood of being ingested by humans. Vended water does not include bottled water.

3. Can an operator of a water vending machine or a retail water facility (or retail water store) bottle water?

A: No. Water vending machine (WVM) operators or retail water facility (RWF) operators are not allowed to bottle water because both WVMs and RWFs are not water bottling plants. A WVM is a self-service device from which vended water is dispensed upon insertion of coins, tokens, or upon receipt of payment by any other means to containers of a customer, who come to the device to obtain water. A RWF is any commercial establishment where vended water is sold and placed in the containers of a customer, who come to the establishment to obtain water.

4. Can an operator of a WVM or a RWF deliver his or her water to a customer's home or office?

A: No. The law does not allow operators of WVMs or RWFs to deliver water to their customers' homes or offices. It is because a WVM or a RWF has been classified, by law, as a device or a commercial establishment to which customers bring their containers to obtain vended water.

5. Can a RWF operator clean and/or sanitize customers' containers?

A: No. RWF operators should not clean and/or sanitize their customers' containers on their premise. It is the customer's responsibility to bring clean containers to a RWF to obtain vended water.

6. What are different types of bottled water?

A: Bottled waters are classified in accordance with their definitions as described in the state laws and the federal regulations that California adopts. They cannot contain sweeteners, acidifying agents (e.g., citric acid), vitamins, or chemical additives. Bottled waters, except for mineral water, must contain less than 500 parts per million (ppm) of total dissolved solids (TDS).

Spring Water: Water derived from an underground formation from which water flows naturally to the surface of the earth. Spring water must be collected only at the spring or through a borehole tapping the underground formation feeding the spring. There must be natural force causing the water to flow to the surface through a natural orifice. Spring water collected with use of external force must be from the same underground stratum as the spring, as shown by a measurable hydraulic connection using a hydrogeologically valid method between the borehole and the natural spring, and must have all the physical properties, before treatment, and be of the same composition and quality, as the water that flows naturally to the surface of the earth through the spring's natural orifice. Spring water must not be under the direct influence of surface water.

Mineral Water: Water which contains more than 250 ppm TDS and comes from a source originating from a protected underground water source. No minerals are allowed to be added to this water. The label of mineral water must bear a mineral content statement if its TDS is less than 500 ppm or greater than 1,500 ppm. For example, if a mineral water contains less than 500 ppm of TDS, it must bear a statement "Low Mineral Content" on its label. If it contains more than 1,500 ppm of TDS, its label must state "High Mineral Content." If its TDS is between 500 and 1,500 ppm, however, no statement will be necessary.

Well Water: Water which is extracted, through a hole (bored, drilled or otherwise constructed), from a subsurface saturated zone that is not under the direct influence of surface water.

Artesian Water: Water which would meet the definition of well water except it taps a confined aquifer in which the water stands at some height above the top of the aquifer. Another suitable name is "Artesian Well Water".

Purified Water: Water that has been processed by distillation, deionization, reverse osmosis, or other suitable means to reduce its TDS to less than 10 ppm. The source can be from a spring, well or a public drinking water supply. Other suitable names include "Demineralized water," "Distilled Water," "Deionized Water," and "Reverse Osmosis Water," depending on the corresponding treatment process used.

Sparkling Bottled Water: Bottled water that, after treatment and possible displacement of carbon dioxide, contains the same amount of carbon dioxide from the source that it had at emergence from the source. Soda water, seltzer water and tonic water are considered soft drinks, not bottled water.

Sterile Water or Sterilized Water: Bottled water that meets the requirements under "Sterility Tests" <71> in the U. S. Pharmacopeia, 23rd Revision, January 1, 1995. This type of bottled water is very difficult to find, or non-existent, in the market place. For example, as of March, 2006, no licensed bottled water that meets the definition for "sterile water" (or sterilized water) is marketed in California.

Flavored Water: Bottled water with natural or added carbonation may be prepared with added flavors, extracts, essences, or fruit juice concentrates derived from a spice or fruit and comprising less than 1 percent by weight of the final product. The final product must not contain sweeteners or additives other than the flavors, extracts, essences, or fruit juice concentrates and carbon dioxide.

Drinking Water and Potable Water: They are generic names of bottled water. Any bottled water may be named as "Drinking Water," or "Potable Water."

7. How does the state regulate bottled water and vended water that are marketed or distributed in California?

A: Manufacturers of bottled water (regardless of whether they are produced in-state, out-of-state, or in foreign countries) and vended water must be licensed and regulated by the Department of Health Services' Food and Drug Branch (FDB) in order to sell or distribute their products in California. FDB inspects in-state bottlers and vendors for sanitation, manufacturing operation control, equipment and quality control procedures, testing requirements, record keeping, labeling, and advertising. For bottlers located out-of-state or in foreign countries, FDB relies on the inspection by the pertinent regulatory agency of the state or the country where the plant is located.

8. Are bottlers and vendors required to obtain licenses to distribute or sell their water products in California?

A. Yes. State law requires that all water bottlers (regardless of whether located in-state, out-of-state, or in a foreign country), private source operators, bottled water distributors, retail water facility operators, water vending machine operators and water haulers obtain a license to bottle, collect, treat, hold, distribute, haul, vend, or sell water in California. FDB issues 6 different types of licenses: 1) water bottling plant (in-state or out-of-state including those in foreign countries), 2) private water source operator, 3) water hauler, 4) retail water facility, 5) water vending machine operator, and 6) bottled water distributor. Bottled water distributor license is issued to those who deliver water in returnable bottles (e.g., 4- or 5-gallon bottles) from a bottler to a customer's home or office and do the service of replacing bottled water on a customer's cooler. Those who deliver or sell bottled water packaged in single serve bottles (i.e., one time use only-bottles which are found on supermarket shelves; e.g., 7 oz size-bottled water) are not required to obtain a bottled water distributor license.

9. Where can I obtain a license application and procedures for obtaining a license?

A: All license applications and procedures can be downloaded/obtained at the FDB website, <http://www.dhs.ca.gov/fdb>. You may also contact the FDB Water Licensing Desk at (916) 650-6515.

10. What are the applicable laws and regulations to comply with in order to obtain a license?

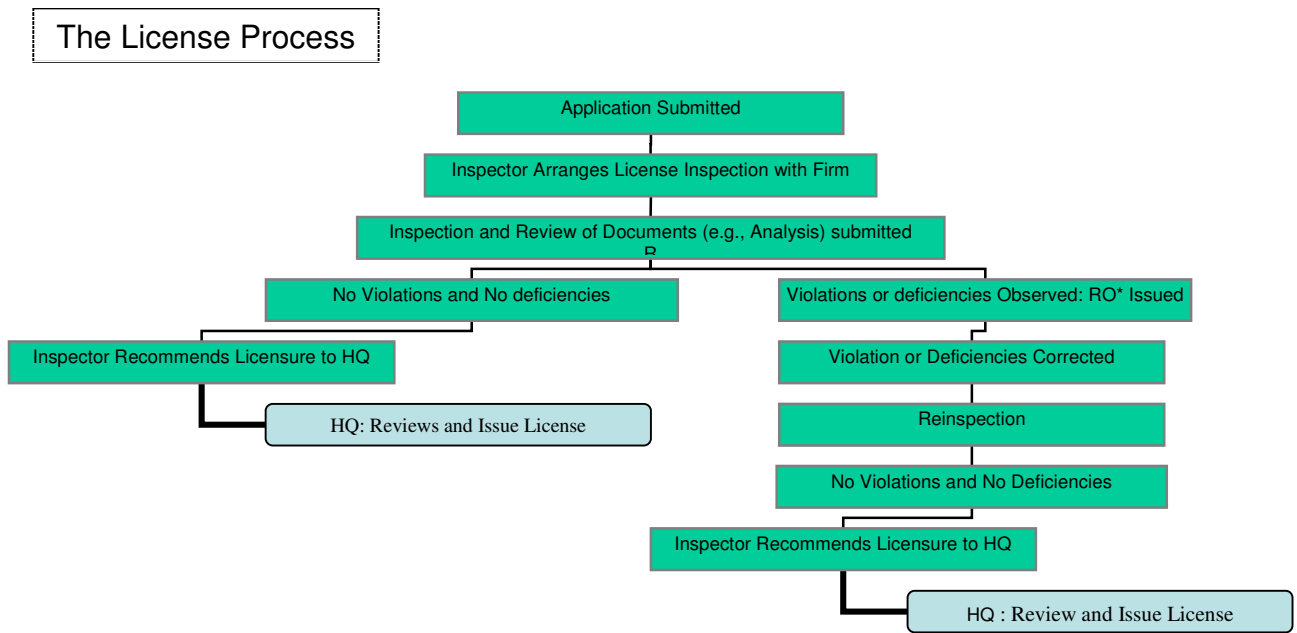
A: The applicable laws are:

- 1) California Health and Safety Code (H&SC) 111070 to 111195;
- 2) H&SC (CURFFL) Sections 114200-114245 (vending machines);
- 3) California Administrative Code, Title 17, CCR Sections 12245 to 12280 (Food Plant sanitation);
- 4) Title 21 Code of Federal Regulations (21 CFR) Sections 165.3 and 165.110; and
- 5) 21 CFR Part 129 and 110.

The H&SC Sections and the federal regulations (21 CFR) can be downloaded at the websites, <http://www.leginfo.ca.gov/calaw.html> and <http://www.gpoaccess.gov/cfr/index.html>, respectively. The CCR Sections can be downloaded at the website, <http://weblinks.westlaw.com/toc/default.aspx?Abbr=ca%2Dadc&Action=ExpandTree&AP=CAT17D1CH5BZZCAAAR7CAE&ItemKey=CAT17D1CH5BZZCAAAR7CAE&RP=%2Ftoc%2Fdefault%2Ewl&Service=TOC&RS=WEBL6.03&VR=2.0&SPa=CCR-1000&fragment#CAT17D1CH5BZZCAAAR7CAE>.

11. How does FDB process the license application?

A: The process for handling an application is briefly described as:



* RO: Report of Observation

12. Does imported bottled water have to meet the same quality standards as those bottled in-state?

A: Yes. Bottled water from other states or foreign countries must meet the same quality and identity standards as those produced in-state.

13. How would you characterize the differences in the way the state regulates tap water vs. bottled water and vended water?

A: The regulations for tap water are different from those for bottled water mainly because their sources are different. Source waters for producing public drinking water include lakes, rivers, and wells, while bottled water must be produced only from already approved sources (e.g., public drinking water or a licensed private water source). The key purpose of treatments for tap water is to make the water safe. Accordingly, the regulations for tap water are to meet that purpose. On the other hand, a water bottling plant, a water vending machine, or a retail water facility treats already safe water to improve its quality (mainly clarity, flavor, and taste) by treatment with filtration processes (such as activated carbon, reverse osmosis, micro-filtration) and disinfection (such as ozone, ultraviolet light). Since the source water, purpose, and the types of equipment used for tap water are different from those for bottled water and vended water, comparing the regulations for the two different groups of products is not appropriate.

14. Are bottled water and vended water safer than tap water?

A: Bottled water and vended water begin with tap water (public drinking water) or water from a licensed private water source that meets all regulatory requirements, and then receive further treatment to enhance the quality (taste, smell, clarity, etc). This treatment for bottled water/vended water usually consists of one or more filtration and disinfection processes and requires adherence to all relevant Good Manufacturing Practices required under statute. Bottled water, vended water, and tap water are safe for consumers.

15. If the source of bottled water or vended water is from a public drinking water system (or a municipal source), does the source have to be indicated in the label?

A: When the source for bottled water comes from a public drinking water system, the product label must state that the bottled water is from “a public drinking water” or “from a municipal source.” However, if the water has been purified to have less than 10 ppm TDS (to meet the legal definition for purified water), it does not have to bear such statement on its label.

Water vending machines and retail water facilities must display, in a position clearly visible to customers, the fact that their source water is obtained from an approved public water supply.

16. Does California have different labeling requirements for bottled water from those of the U.S. FDA (FDA)?

A: California adopts all federal labeling requirements for bottled water, but additionally requires that contact information be stated on the label of bottled water (e.g., telephone number, mailing address, or e-mail address of the bottler or brand owner). In the case of products in non-returnable bottles, the contact information can be provided on each billing statement. California has adopted a definition for “flavored water,” which has not been established in the federal regulations.

17. Where are the pertinent labeling laws and regulations on bottled water and vended water?

A: The applicable labeling laws can be found in the:
1) California Health and Safety Code (H&SC) 111070 to 111195, and
2) 21 CFR Parts 101 through 104 and Section 165.110(a).

H&SC Sections and the federal regulations (21 CFR) can be downloaded at the websites, <http://www.leginfo.ca.gov/calaw.html> and <http://www.gpoaccess.gov/cfr/index.html>, respectively. FDB has a brochure that

provides the general information on food labels, including those for bottled water (visit the FDB website, <http://www.dhs.ca.gov/fdb/HTML/food/procfdrg.htm>; subject: Food Labels). Additional information that must be submitted regarding the designation of water (e.g., spring water) as part of the licensure process is specified in the “Procedure for obtaining an in-state or out-of-state water bottling plant license” (visit the FDB website, <http://www.dhs.ca.gov/fdb/HTML/General/fdbapps.htm>)

18. Does California have different water quality standards for bottled water from those of FDA?

A: California adopts all federal water quality requirements for bottled water except for trihalomethanes (THMs). The federal upper limit for THMs is 80 parts per billion (ppb), while California’s upper limit is 10 ppb.

19. Where are the pertinent laws and regulations on the quality of bottled water and vended water?

A: The applicable laws are:

- 1) California Health and Safety Code (H&SC) 111080, and
- 2) 21 CFR Section 165.110 (b).

The H&SC Section and the federal regulation (21 CFR) Section can be downloaded at the websites, <http://www.leginfo.ca.gov/calaw.html> and <http://www.gpoaccess.gov/cfr/index.html>, respectively.

20. How often is bottled and vended water required to be tested?

A: The law requires that bottled water and source water be analyzed for physical, chemical and radiological parameters at least once per year. Bottlers and private water source operators (PWSO) must also test water for the presence of coliform bacteria (i.e., “total coliforms”) at least weekly for each of their water products (i.e., finished product by bottlers; source water by PWSO).

Operators of retail water facilities and water vending machines are required to test their water for coliform bacteria and total dissolved solids (if purified water is dispensed) at least once per 6 months. Water haulers should test water for coliform bacteria: 1) at the first water load after their hauling tanks have been cleaned and sanitized, and 2) once per 30 days during months when water hauling is performed.

21. Where can I test the water?

A: If your firm is located in California, the required testing must be performed at a laboratory certified for the particular analysis by the California Department of Health Services' Environmental Laboratory Accreditation Program (ELAP). A list of certified laboratories near you can be downloaded at the ELAP website, <http://www.dhs.ca.gov/ps/ls/ELAP/default.htm> or obtained by contacting ELAP at (510) 620-3155. If your firm is located out-of-state, the test can be done by laboratories certified by the primary enforcement authority in those states (or foreign countries) which have been granted primacy by the U.S. Environmental Protection Agency, or laboratories certified (accredited) by a third-party organization acceptable to a primacy state. Other non-required tests (e.g., internal quality control testing), however, may be performed in-house.

22. What is the bottled water and source water tested for?

A: On an annual basis, bottlers and private source water operators must analyze water for: 1) physical characteristics (e.g., color, odor, turbidity, total dissolved solids), 2) inorganic substances (e.g., aluminum, antimony, arsenic, cadmium, mercury), 3) volatile organic chemicals (e.g., benzene, carbon tetrachloride), 4) non-volatile synthetic organic substances (e.g., alachlor, atrazine), 5) radioactivity (e.g., combined radium-226 and -228, gross alpha and beta particles, uranium), and 6) disinfection byproducts if disinfected (e.g., bromate, chlorite). On weekly basis, they must test water for coliform bacteria. The full list of substances to be analyzed can be downloaded at the website, <http://www.dhs.ca.gov/fdb/HTML/General/fdbapps.htm> (subject: Water Analysis-chemical, physical, radiological & bacteriological).

23. How long can I store bottled water?

A: Generally, bottled water has an indefinite shelf life if it is produced in accordance with the laws/regulations and remains unopened. Therefore, expiration dates (or shelf-life) on bottles are voluntary and may reflect concerns for taste and odor rather than safety. Many bottlers generally give a two-year shelf-life on their products. Bottled water should be stored, in a cool location away from direct sunlight, and not stored adjacent to any chemicals or solvents.

24. Can I store and use bottled water in case of emergency?

A: Yes. You can store large quantities of bottled water in a basement or cold storage area in case of possible problems with public drinking water supplies, in the aftermath of a natural disaster. It is generally recommended to replace the bottled water every year (considering that some bottled waters do not have expiration dates, and/or that some time has already passed when bottled waters are purchased and stored).

25. Can bottled water, including distilled water, have bacteria in it?

A: Like most foods, a small number of bacteria may be found in many bottled waters sold for drinking purposes. Bottled waters, except for some of those imported from foreign countries, have been disinfected to remove harmful microorganisms before being bottled. However, the disinfection, usually by ultraviolet light or ozone, is not intended to sterilize water. Rather, it is intended to destroy harmful microorganisms and substantially reduce the total number of other microorganisms. The surviving microorganisms (e.g., heterotrophic bacteria) are not considered to be a health hazard to general populations.

Only the bottled waters identified as sterile (or sterilized) are free of bacteria. In order to be identified as sterile or sterilized water, the water must meet the required "Sterility Tests" <71> in the U. S. Pharmacopeia, 23rd Revision, January 1, 1995. However, such bottled water is very difficult to find in the market place. For example, as of March, 2006, no licensed bottled water that meets the definition for "sterile water" (or sterilized water) was being marketed in California. Generally, sterile products are reserved for pharmaceuticals.

26. Can I use bottled water to clean contact lenses?

A: No. Only the over the counter drug products designed for use with contact lenses should be used. These products are sterilized and are safe for this use.

27. Some bottlers and vendors advertise that their waters are UV-sterilized or ozone-sterilized. Does it mean that they are producing sterilized water?

A: No. Such terms are misleading to consumers because neither UV nor ozone can sterilize water. At certain dose levels, however, they can destroy harmful microorganisms and substantially reduce the total number of other microorganisms in water. Thus, the terms must be corrected to "UV-disinfected" or "ozone-disinfected." Accordingly, their products are not "sterilized water."

28. Who has the responsibility for maintaining a bottled water cooler?

A: A bottled water cooler is an independent device that can be used to dispense water from removable 4- to 5-gallon plastic bottles usually positioned on top of the unit. Bottle water coolers can be cold units that can dispense only cold water, or hot and cold units that can dispense both hot and cold water. Like a refrigerator in your house, the owner has the responsibility to clean and keep the cooler in sanitary condition. If the owner has rented or leased the cooler from a bottler (or a bottled water distributor), it may be the responsibility of the bottler (or the bottled water distributor) to maintain or periodically replace the cooler, depending on the terms of the contract.

29. How can I clean and sanitize a bottled water cooler?

A: If you rented or leased a bottled water cooler, it is likely that the provider (bottler or distributor) has the responsibility to clean and sanitize, or replace the cooler periodically. If you purchased the cooler and own it, you may have to clean and sanitize the cooler on your own. In that case, it is best to follow the cleaning/sanitizing procedure or instructions provided by the cooler manufacturer or the distributor of your bottled water. However, if you cannot locate the procedure/instructions or if the procedure/instructions are not available, you may use the following procedure **[please wear eye protection and gloves to protect yourself]**: 1) unplug cord from electrical outlet of cooler; 2) remove empty bottle; 3) drain water from the reservoir(s) through faucet; 4) make a solution containing one part of vinegar diluted with three parts of water (the quantity should be sufficient enough to fill the reservoir), fill the reservoir with the solution and hold for about 5 minutes (to clean it of scale), drain the solution through faucet, rinse the reservoir with water [and/or scrub the reservoir(s) by hand, if applicable]; 5) prepare a disinfecting solution by adding 1 and 1/2 teaspoons (about 8 milliliter) of a household chlorine bleach (5.25% active chlorine; see product label for the concentration of active chlorine; use unscented chlorine bleach if possible) to 1 gallon of tap water. [This solution will have approximately 100 ppm chlorine]; 6) wash reservoir thoroughly with the disinfecting solution and let stand for at least two minutes (to be effective), but not more than five minutes (to minimize possible corrosion); 7) drain the disinfecting solution from reservoir through faucet(s); and 8) rinse reservoir thoroughly with clean tap water and drain the rinse water through faucets. Repeat rinsing until you do not detect traces of chlorine odor. **[Warning: Please be careful not to spill or splash the disinfecting solution and rinse water on clothes or carpets since they would likely become discolored. Discard any leftover-disinfecting solution to prevent children or pets from accidentally drinking it.]**

30. What is the good practice for replacing bottled water on a cooler?

A: It is best to follow the procedure recommended by the bottled water distributor, or cooler manufacturer. If the procedure is not available, you may use the following procedure: 1) wear new, clean gloves (e.g., latex) before beginning the procedure. [If you want to use a pair of used-gloves, however, the gloves must be disinfected, prior to reuse, by dipping them in a disinfecting solution. The disinfecting solution may be prepared by adding 1 and 1/2 teaspoons (about 8 milliliter) of household chlorine bleach (use unscented chlorine bleach if possible) to one gallon of tap water]; 2) wipe the top and neck of the new bottle with a paper towel dipped in the disinfecting solution. Rubbing alcohol may also be used, but must be completely evaporated before placing the bottle in the cooler; 3) remove cap from new bottle; and 4) place new bottle on the cooler. **[Warning: Please be careful not to spill or splash the disinfecting solution on clothes or carpets since it would likely discolor them. Discard any**

leftover-disinfecting solution to prevent children or pets from accidentally drinking it.]

31. Are the one-time use plastic bottles safe to reuse?

A: One-time use plastic bottles should not be reused. Reused bottles may be contaminated with disease-causing bacteria and other microorganisms. Consumers should return empty plastic bottles to their nearest recycling center for refund or discard them into the appropriate recycling container. Information regarding the location of the nearest recycling center may be obtained from the point of bottled water purchase, or by calling the California Department of Conservation (CDC) at 1-800-RECYCLE, or by visiting the CDC's website: <http://www.bottlesandcans.com/where.php>.

32. Who should I contact if I experience illness after drinking bottled water or vended water?

A: If you become ill after eating any food including bottled water and vended water, you should contact or visit your physician immediately. If your physician indicates that your illness may have been due to the food you ate or drink, please call your county or city health department listed in the white pages of your telephone directory. In addition to your local health department, you may report your illness to the "FDB Consumer Complaint Hotline" at 1-800-495-3232.

33. Who should I contact to find out if the bottler or vendor of water that I purchased water from has a valid license?

A: You may call any of the FDB offices near you (You should be able to locate its phone number in the white pages of your telephone directory), or the FDB Water Licensing Desk at (916) 650-6515.